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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/602,785	06/24/2003	Kevin S. TenHuisen	ORT1596 DIV1	1667

27777 7590 08/10/2004

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EXAMINER

LUCAS, ZACHARIAH

ART UNIT

PAPER NUMBER

1648

DATE MAILED: 08/10/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/602,785

Applicant(s)

TENHUISEN ET AL.

Examiner

Zachariah Lucas

Art Unit

1648

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 June 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 41 and 42 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 41 and 42 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 6-24-2003.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____.

DETAILED ACTION

1. Currently, claims 41 and 42 are pending and under consideration in this application.

Information Disclosure Statement

2. The information disclosure statement (IDS) submitted on June 24, 2003, is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement has been considered by the examiner.
3. The reference listed as Cerami et al, Application 10/017457 has been considered to the extent of the contents of U.S. PG Pub 20030118630, which publication is the pre-grant publication of the indicated application,

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 41 and 42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cerami et al., WO 99/44583 (of record in the June 2003 IDS), in view of the teachings of Sternick et al. (WO 85/03635- of record in the June 2003 IDS). These claims are drawn to methods for obtaining immune cells from an animal comprising implanting into the animal an immune modulation device, and harvesting from the device immune cells that migrated into it. The device

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is claimed as comprising an impermeable biopolymer shell having pores of sufficient size to allow the ingress and egress of immune cells, and a fibrous scaffolding within the shell having a sufficient quantity of an antigen or chemotactic agent sufficient to provoke an immune response.

Cerami teaches an implantable device similar to that described by the claims, except that the scaffolding inside the shell comprises not a fibrous material, but a porous matrix. Page 3. The device is disclosed s useful for the purpose of harvesting immune cells for later reintroduction into the subject. Page 4, lines 23-27. Thus, the reference teaches all the limitations of the claimed methods except the use of a fibrous scaffolding for the antigens within the device. The reference further teaches that the devices disclosed therein are useful both for the modulation of an immune response, and for the harvesting of immune cells.

Sternick teaches a method for the induction of an immune response in an animal by implanting a biocompatible substrate with an antigen. Pages 4-5. Among the materials that the reference teaches are useful as the substrate in such methods are various for of fibers and meshes. Page 4, lines 17-25. Because the substrate of the reference acts in a similar manner to those of the support in Cerami (i.e. as a support for antigens in a device for the stimulation of immune cells), it would have been obvious to those in the art that such fibrous matrices are functionally equivalent to the spongy matrix of Cerami. Because those in the art would have recognized that the matrices are functionally equivalent, it would have been obvious to those in the art to substitute the fibrous matrix of Sternick for spongy matrix of Cerami. The combined teachings of the references therefore render the claimed methods obvious.

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6. Claims 41 and 42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cerami et al., WO 99/44583 (of record in the June 2003 IDS), in view of the teachings of Li et al. (U.S. Patent 6,303,136). The claims and the teachings of Cerami have been described above. As was indicated above, Cerami teaches method similar to that of the claimed methods, except that the device used in Cerami comprises a spongy, rather than a fibrous, matrix within the device.

The Li reference also teaches an implantable device for the containment of cells. While this device is not described as useful for the capture of immune cells, it is intended for the encapsulation of cells in a host environment. Column 1. Because Cerami teaches that one function of the immune device described therein is for the harvesting of immune cells, those in the art would have looked to Li as relevant art for the implantable devices for the containment of cells.

The structure of the device described by Li (col. 1, lines 17-26) is similar to that of the Cerami device. The devices differ in that, in the Li device, the outer membrane is impermeable to large molecules and cells, whereas Cerami's device is made permeable to immune cells through perforation of the outer shell. Additionally, Li teaches that the cells within the device are preferably placed on a fibrous scaffolding (col 2, lines 29-43), whereas Cerami teaches a porous matrix, and indicates that such matrix may be a sponge-like material (page 9, lines 1-6). Because Li teaches a device for the encapsulation of cells, and Cerami teaches a device for the capture of cells, it would have been apparent to those in the art that the matrices taught by Li and Cerami were functionally equivalent as providing support for cells in an implanted device. It would therefore have been obvious to those in the art to have used a fibrous matrix such as the one disclosed in Li in the Cerami device.

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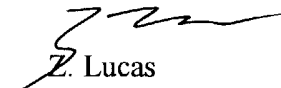
Those in the art would have had a reasonable expectation of success in the combination because other teachings in the art indicate that the multiple materials made be used in to form matrices for implantable immune devices. See e.g., WO 85/03635, pages 4-5 (of record in the June 2003 IDS). Thus, the combined teachings of Cerami and Li render the claimed methods obvious.


Conclusion

7. No claims are allowed.
8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zachariah Lucas whose telephone number is 571-272-0905. The examiner can normally be reached on Monday-Friday, 8 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Z. Lucas
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8/7/04